

### **REMARKS/ARGUMENTS**

The Final Office Action of May 14, 2008 has been carefully reviewed and this paper is Applicants' response thereto. Claims 1–39 are pending in the application. Claims 1–19 and 21–39 were rejected under 35 USC §102(e) or 35 USC §103(a) in view of U.S. Pub. No. 2002/0013612 to Whitehurst (“Whitehurst”). Claim 20 was rejected under 35 USC §103(a) as being unpatentable over Whitehurst in view of U.S. Pub. No. 2002/0013613 to Haller *et al.* (“Haller”). In response, Applicants respectfully traverse the rejections in view of the remarks that follow.

#### **Rejection under 35 USC §102 and §103 - Whitehurst**

*Claims 1–19 and 21–39 were rejected under 35 USC §102(e) as anticipated by or, in the alternative, under 35 USC §103(a) as obvious over Whitehurst. Claim 20 was rejected under 35 USC §103 as being unpatentable over Whitehurst in view of Haller. Applicants respectfully traverse this rejection.*

As an initial matter, no rationale was provided for why claims 6, 24, 25, 28–31, 33–36, and 38 are believed to be unpatentable in view of Whitehurst. Furthermore, claim 38 is a new claim prior to the most recent office action. Therefore, there is no rationale for why Whitehurst is believed to render claim 38 unpatentable. Accordingly, a notification that at least claim 38 contains allowable subject matter is respectfully requested. Alternatively, the Applicants respectfully request an indication of the rationale being used to support the rejection of claims 6, 24, 25, 28–31, 33–36, and 38.

#### **Independent Claim 1**

Independent claim 1 recites the feature of “a first external component configured to receive data from the implantable component and to support a second treatment therapy mode in accordance with the data.” As recited in claim 1, therefore, the data used to support the second treatment therapy is based on data received from the implantable component. Claim 1 further recites the feature of “wherein the implantable component is configured . . . to automatically switch to the second treatment therapy mode when the external component is coupled to the communications channel, where, in operation, the second treatment therapy mode is responsive to the data being transported over the communications channel.” (emphasis added). The Office

Action has failed to support its suggestion that Whitehurst discloses these features, especially the automatic switching feature and that the second treatment therapy mode responds to the data transported over the communications channel as recited in claim 1.

In support of the rejection, the Office has pointed to paragraph 92 of Whitehurst, which is provided below:

**[0092]** Function 1: If necessary, transmit electrical power from the external electronic appliance 230 via appliance 220 to SCU 130 in order to power the device and/or recharge the power source/storage device 180. External electronic appliance 230 may include an automatic algorithm that adjusts electrical and/or drug stimulation parameters automatically whenever the SCU(s) 130 is/are recharged.

Whitehurst, pg. 8, ¶ 92. This portion of Whitehurst fails to disclose “a first external component configured to receive data from the implantable component and to support a second treatment therapy mode in accordance with the data” but instead merely discloses an external component configured to “adjust . . . parameters” for a treatment mode during charging, without more. In other words, to the extent the above portion discloses a second treatment therapy mode, the second treatment therapy mode is not in accordance with the data but instead is irrespective of the data. Therefore, this paragraph of Whitehurst cannot fairly be said to disclose the automatic switching between modes as recited in claim 1.

The Office Action also suggested that paragraph 90 discloses a mode of switching. However, paragraph 90 discusses the use of a separate or specialized implantable device and at most discloses the possibility of transmitting information to an external device or to implanted SCUs. Notably, there is no suggestion that Whitehurst contemplated, suggested or disclosed the feature “wherein the implantable component is configured . . . to automatically switch to the second treatment therapy mode when the external component is coupled to the communications channel.” Instead, this section of Whitehurst at most discloses that information may be transmitted from one implanted device to an external device or to a separate implanted device.

Regarding the suggestion that it would be obvious to include a switching mode, Applicants respectfully submit the Office Action fails to provide any rationale for why the

system of Whitehurst should be so modified or what the basis for such a modification would be. In particular, there is no disclosure for how the reprogramming done by a user, which the Office Action appears to be reading as a closed-loop mode, could be done automatically. Instead, it appears that Whitehurst merely discloses the ability to couple an external component to an implanted device and modify the setting of the implanted device but fails to disclose the above recited features of claim 1. Therefore, for at least the above reasons Whitehurst fails to disclose, suggest or teach all the features of claim 1. Accordingly, claim 1 is patentable over Whitehurst.

### **Dependent Claims 2-10 and 38**

Claims 2-10 and 38, which depend from claim 1, are patentable for at least the reasons that claim 1 is patentable and for the additional feature recited therein.

Additionally, claim 2 recites that the multi-modal device system further comprises “a programmer configured to directly communicate with the implantable component through the external component . . . to support a third treatment therapy mode.” (emphasis added). The Office Action contends that “the programmer is the patient who directly communicates with the SCU via a HHP 190.” (Office Action, page 5) (emphasis added). However, the Applicants respectfully argue that the programmer as recited in claim 2 is not a person (such as a patient as the Office Action contends), but a machine. This programmer is recited in claim 3 to be configurable, as a machine would be. A person is not “configurable.” Furthermore, the specification provides additional supporting evidence that this programmer is a machine and should not be confused with a person.

The external system 100 utilizes a programmer 109, which in the embodiment is a commercially available personal computer and an operating system configured with custom external system application software. Those skilled in the art will appreciate that any general-purpose computing device may be used including, but not limited to, a hand-held device.

(Osorio, para [0048]) (emphasis added). Nowhere in the application, does the Applicant refer to the programmer as a person, whether it is the patient or clinician, as the Office Action has characterized the programmer. Claim 3 also recites that the multi-modal medical device comprises “a programmer configured to indirectly communicate . . .” (emphasis added) similar to claim 2. Therefore, for at least the above reasons Whitehurst fails to disclose, suggest or

teach all the features of claims 2 and 3. Accordingly, for at least these reasons, claims 2 and 3 are patentable over Whitehurst.

Additionally, the Office Action states that claim 10 is not patentable over Whitehurst because the Examiner considers “the additional module or external component to be the clinician programming device CPS 192, which is capable of communicating with the SCU via the HHP 190.” (Office Action, pg. 5). However, claim 10 recites that the multi-modal medical device system comprises “another external component that is coupled to the first external component.” (emphasis added). The Examiner’s above consideration in reference to claim 10 does not disclose, teach or suggest that there is a second or “another external component” as claim 10 recites. Therefore, for at least the above reasons Whitehurst fails to disclose, suggest or teach all the features of claim 10. Accordingly, for at least these reasons, claim 10 is patentable over Whitehurst.

Additionally, claim 38 recites the feature of “wherein the data includes signal measurements and the first mode is open-loop treatment therapy and the second mode is closed-loop treatment therapy, wherein, in operation, the closed loop treatment therapy provided is directly responsive to the signal measurements.” The Office has not pointed to any portion of Whitehurst as disclosing this feature. Indeed, the Office Action admits that closed-loop treatment requires the use of feedback, however, Whitehurst fails to disclose the feedback being signal measurements. Therefore, for at least the above reasons Whitehurst fails to disclose, suggest or teach all the features of claim 38. Accordingly, claim 38 is patentable over Whitehurst.

#### **Claims 11 and 12**

Independent claim 11 recites features similar to the above feature of claim 1, thus Whitehurst also fails to disclose at least one feature of this independent claim. Therefore, claim 12, which depends from claim 11, is patentable for at least the reasons that claim 11 is patentable and for the additional features recited therein.

Additionally, the Office Action states that claim 12 is not patentable over Whitehurst because the Examiner considers “the additional module or external component to be the clinician programming device CPS 192, which is capable of communicating with the SCU via the HHP 190.” (Office Action, pg. 5). However, claim 12 recites that the multi-modal medical device

system, and specifically the external component, comprises “an additional module that supports an additional treatment therapy mode when the external component is coupled to the implantable component.” The Examiner’s above consideration in reference to claim 12 does not disclose, teach or suggest that there is a second or “additional module” as claim 12 recites. Therefore, for at least the above reasons Whitehurst fails to disclose, suggest or teach all the features of claim 12. Accordingly, for at least these reasons, claim 12 is patentable over Whitehurst.

### **Claims 13–36**

Independent claim 13 recites features similar to the above feature of claim 1, thus Whitehurst also fails to disclose at least one feature of this independent claim. Therefore, claims 14–36, which depend from claim 13, are patentable for at least the reasons that claim 13 is patentable and for the additional features recited therein.

Additionally, the Office Action contends that claims 17 and 18 are not patentable over Whitehurst because Whitehurst “discloses a system and method for treating mood or anxiety disorders, which is a nervous system disorder, by utilizing an implantable system control unit (SCU), electrodes and a pulse generator for treatment.” (Office Action, pg. 5). However, claims 17 and 18 recite the steps of “storing the neurological data by the implantable component,” and “retrieving the neurological data from the implantable component.” (emphasis added). Claim 17 further recites the step of “storing the neurological data by the external component.” (emphasis added). Claim 18 further recites the step of “sending the neurological data to an external site by the external component.” (emphasis added). First of all, the Examiner’s argument above does not discuss Whitehurst disclosing a method that includes storing, retrieving, or sending neurological data. The examiner merely references that Whitehurst discloses a method for treating mood or anxiety disorders by an implantable device, electrodes, and a pulse generator, nothing of which references storing, retrieving, or sending neurological data. Secondly, Applicants have been unable to find any mention of the steps storing, retrieving or sending neurological data being performed by Whitehurst in order to provide a treatment of a nervous system disorder. Therefore, for at least the above reasons Whitehurst fails to disclose, suggest or teach all the features of claims 17 and 18. Accordingly, for at least these reasons, claims 17 and 18 are patentable over Whitehurst.

**Independent Claims 37 and 39**

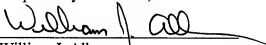
Independent claims 37 and 39 recite features similar to the above features of claim 1, thus Whitehurst also fails to disclose at least one feature of claims 37 and 39. Additionally, claim 37 recites the step of “exchanging neurological data between the implantable component and an external component” and further recites the step of “if the external component and the implantable component are coupled, automatically switching to a closed-loop mode with the external component in accordance with the neurological data.” Claim 39 recites the similar step of “in response to receiving a reply within a predetermined period, providing neurological data to the external component over a communication channel, the neurological data being responsive to the open-loop treatment therapy.” Applicants have been unable to find any mention of such steps being performed by Whitehurst to use neurological data in order to provide treatment of a nervous system disorder. Therefore, for at least the above reasons Whitehurst fails to disclose, suggest or teach all the features of claims 37 and 39. Accordingly, claims 37 and 39 are patentable over Whitehurst.

**CONCLUSION**

All rejections having been addressed, Applicants respectfully submit that the instant application is in condition for allowance, and respectfully solicit prompt notification of the same. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the number set forth below.

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Respectfully submitted,



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